



**EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2014. Scientific Opinion on the substantiation of a health claim related to barley soup “Orzotto” and protection of blood lipids from oxidative damage pursuant to Article 13(5) of Regulation (EC) No 1924/2006**

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## SCIENTIFIC OPINION

### Scientific Opinion on the substantiation of a health claim related to barley soup “Orzotto” and protection of blood lipids from oxidative damage pursuant to Article 13(5) of Regulation (EC) No 1924/2006<sup>1</sup>

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)<sup>2,3</sup>

European Food Safety Authority (EFSA), Parma, Italy

#### ABSTRACT

Following an application from Italsur srl, submitted for authorisation of a health claim pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of Italy, the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver an opinion on the scientific substantiation of a health claim related to barley soup “Orzotto” and protection of blood lipids from oxidative damage. The Panel considers that barley soup “Orzotto”, which is a vegetable mix containing pearled barley, Tuscan Black cabbage, potatoes, “blu savoy” cabbage, purple carrots, “bi-coloured” spinach, “tri-coloured” Swiss chard, onions, red and yellow celery and parsley, is sufficiently characterised. The claimed effect, protection of blood lipids from oxidative damage, may be a beneficial physiological effect. No human intervention studies from which conclusions could be drawn for the scientific substantiation of the claim were provided by the applicant. The Panel concludes that a cause and effect relationship has not been established between the consumption of barley soup “Orzotto” and protection of blood lipids from oxidative damage.

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#### KEY WORDS

Orzotto, barley soup, blood lipids, oxidative damage, health claims

<sup>1</sup> On request from the Competent Authority of Italy following an application by Italsur srl, Question No EFSA-Q-2013-00578, adopted on 11 December 2013.

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<sup>3</sup> Acknowledgement: The Panel wishes to thank the members of the Working Group on Claims: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Marina Heinonen, Ambroise Martin, Hildegard Przyrembel, Yolanda Sanz, Alfonso Siani, Anders Sjödin, Sean (J.J.) Strain, Inge Tetens, Hendrik Van Loveren, Hans Verhagen and Peter Willatts for the preparatory work on this scientific opinion.

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## SUMMARY

Following an application from Italsur srl, submitted for authorisation of a health claim pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of Italy, the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver an opinion on the scientific substantiation of a health claim related to barley soup “Orzotto” and protection of blood lipids from oxidative damage.

The scope of the application was proposed to fall under a health claim based on newly developed scientific evidence. The application included a request for the protection of proprietary data.

The food that is the subject of the health claim is barley soup “Orzotto”, which is a frozen vegetable mix containing pearled barley (*Hordeum vulgare* L.), Tuscan Black cabbage (*Brassica oleracea* L. var. *acephala* (DC) *laciniata*), potatoes (*Solanum tuberosum* L.), “blu savoy” cabbage (*Brassica oleracea* L. var. *capitata*), purple carrots (*Daucus carota* L. var. *sativus*), “bi-coloured” spinach (*Spinacia oleracea* L.), “tri-coloured” Swiss chard (*Beta vulgaris* L. var. *cycla*), onions (*Allium cepa* L.), red and yellow celery (*Apium graveolens* L. var. *dulce*), parsley (*Petroselinum sativum* L. var. *hortense*). The Panel considers that barley soup “Orzotto”, which is the subject of the health claim, is sufficiently characterised.

The claimed effect proposed by the applicant refers to the protection of blood lipids from oxidative damage. The target population proposed by the applicant is the general population. The Panel considers that protection of blood lipids from oxidative damage may be a beneficial physiological effect.

The applicant identified one unpublished human study, 13 published human studies, nine animal studies, eight *in vitro* studies, eight guidelines/consensus opinions and 21 supportive studies as being pertinent to the health claim.

None of the published human, animal, *in vitro* or supportive studies were carried out with, or referred to, a food complying with the characterisation of the food which is the subject of the claim. The guidelines/consensus opinions did not contain data on a food complying with the characterisation of the food which is the subject of the claim. The Panel notes that none of these references can be used for the scientific substantiation of the claim.

Only one study was carried out with the food (i.e. barley soup “Orzotto”) which is the subject of the health claim. This study was an open label single-arm (no control group) intervention in which 38 healthy volunteers consumed daily for two weeks a portion of barley soup “Orzotto”. The Panel considers that no conclusions can be drawn from this uncontrolled (single-arm) study for the scientific substantiation of the claim.

The Panel concludes that a cause and effect relationship has not been established between the consumption of barley soup “Orzotto” and protection of blood lipids from oxidative damage.

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## BACKGROUND

Regulation (EC) No 1924/2006<sup>4</sup> harmonises the provisions that relate to nutrition and health claims, and establishes rules governing the Community authorisation of health claims made on foods. As a rule, health claims are prohibited unless they comply with the general and specific requirements of this Regulation, are authorised in accordance with this Regulation, and are included in the lists of authorised claims provided for in Articles 13 and 14 thereof. In particular, Article 13(5) of this Regulation lays down provisions for the addition of claims (other than those referring to the reduction of disease risk and to children’s development and health) which are based on newly developed scientific evidence, or which include a request for the protection of proprietary data, to the Community list of permitted claims referred to in Article 13(3).

According to Article 18 of this Regulation, an application for inclusion in the Community list of permitted claims referred to in Article 13(3) shall be submitted by the applicant to the national competent authority of a Member State, which will make the application and any supplementary information supplied by the applicant available to the European Food Safety Authority (EFSA).

## STEPS TAKEN BY EFSA

- The application was received on 31/05/2013.
- The scope of the application was proposed to fall under a health claim based on newly developed scientific evidence. The application included a request for the protection of proprietary data.
- The scientific evaluation procedure started on 29/07/2013.
- On 25/09/2013, the Working Group on Claims of the NDA Panel agreed on a list of questions for the applicant to provide additional information to accompany the application, and the clock was stopped on 10/10/2013, in compliance with Article 18(3) of Regulation (EC) No 1924/2006.
- On 23/10/2013, EFSA received the requested information and the clock was restarted, in compliance with Article 18(3) of Regulation (EC) No 1924/2006.
- During its meeting on 11/12/2013, the NDA Panel, having evaluated the data submitted, adopted an opinion on the scientific substantiation of a health claim related to barley soup “Orzotto” and protection of blood lipids from oxidative damage.

## TERMS OF REFERENCE

EFSA is requested to evaluate the scientific data submitted by the applicant in accordance with Article 16(3) of Regulation (EC) No 1924/2006. On the basis of that evaluation, EFSA will issue an opinion on the scientific substantiation of a health claim related to: barley soup “Orzotto” and protection of blood lipids from oxidative damage.

## EFSA DISCLAIMER

The present opinion does not constitute, and cannot be construed as, an authorisation for the marketing of barley soup “Orzotto”, a positive assessment of its safety, nor a decision on whether barley soup “Orzotto” is, or is not, classified as a foodstuff. It should be noted that such an assessment is not foreseen in the framework of Regulation (EC) No 1924/2006.

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<sup>4</sup> Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods. OJ L 404, 30.12.2006, p. 9–25.

It should also be highlighted that the scope, the proposed wording of the claim, and the conditions of use as proposed by the applicant may be subject to changes, pending the outcome of the authorisation procedure foreseen in Article 18(4) of Regulation (EC) No 1924/2006.

## INFORMATION PROVIDED BY THE APPLICANT

**Applicant’s name and address:** Italsur srl, Contrada Pianura Vomano, 64024 Notaresco, Teramo, Italy.

The application includes a request for the protection of proprietary data for one unpublished study (Bacchetti and Ferretti, unpublished), in accordance with Article 21 of Regulation (EC) No 1924/2006.

### Food/constituent as stated by the applicant

According to the applicant, the food that is the subject of the health claim is the barley soup “Orzotto”, which is a frozen mix containing pearled barley, Tuscan Black cabbage, potatoes, “blu savoy” cabbage, purple carrots, “bi-coloured” spinach, “tri-coloured” Swiss chard, onions, red celery and yellow celery, parsley.

### Health relationship as claimed by the applicant

According to the applicant, the daily inclusion of a portion of frozen barley soup “Orzotto” in a balanced and varied diet reduces oxidative damage of blood lipids.

### Wording of the health claim as proposed by the applicant

The applicant has proposed the following wording for the health claim: “Contributes to the protection of blood lipids from oxidative damage”.

### Specific conditions of use as proposed by the applicant

The applicant has proposed a daily intake of a portion of 250 g barley soup “Orzotto” for two weeks. Consumption should be included in the normal diet as a side dish and no specific time of consumption or accompanying meal or preparation is required.

The target population as proposed by the applicant is the general population.

## ASSESSMENT

### 1. Characterisation of the food/constituent

The food that is the subject of the health claim is barley soup “Orzotto”, which is a frozen vegetable mix containing pearled barley, Tuscan Black cabbage, potatoes, “blu savoy” cabbage, purple carrots, “bi-coloured” spinach, “tri-coloured” Swiss chard, onions, red and yellow celery, parsley.

The detailed composition of the vegetable mix was provided, i.e. ## % pearled barley (*Hordeum vulgare* L.), ## % Tuscan Black cabbage (*Brassica oleracea* L. var. *acephala* (DC) *laciniata*), ## % potatoes (*Solanum tuberosum* L.), ## % “blue savoy” cabbage (*Brassica oleracea* L. var. *capitata*), ## % purple carrots (*Daucus carota* L. var. *sativus*), ## % “bi-coloured” spinach (*Spinacia oleracea* L.), ## % “tri-coloured” Swiss chard (*Beta vulgaris* L. var. *cycla*), ## % onions (*Allium cepa* L.), ## % red celery (*Apium graveolens* L. var. *dulce*), ## % yellow celery (*Apium graveolens* L. var. *dulce*), and ## % parsley (*Petroselinum sativum* L. var. *hortense*).

Details on the composition (e.g. vitamins, minerals, polyphenol compounds) of the vegetable mix in relation to the claimed effect, an overview of the manufacturing process, stability data and information regarding batch-to-batch variability were provided.

The Panel considers that the food, barley soup “Orzotto”, which is the subject of the health claim, is sufficiently characterised.

## 2. Relevance of the claimed effect to human health

The claimed effect proposed by the applicant refers to the protection of blood lipids from oxidative damage. The target population proposed by the applicant is the general population.

Reactive oxygen species (ROS) including several kinds of radicals are generated in biochemical processes (e.g. respiratory chain) and as a consequence of exposure to exogenous factors (e.g. radiation and pollutants). These reactive intermediates can damage molecules such as DNA, proteins and lipids if they are not intercepted by the antioxidant network which includes free radical scavengers such as antioxidant nutrients.

The Panel considers that protection of blood lipids from oxidative damage may be a beneficial physiological effect.

## 3. Scientific substantiation of the claimed effect

The applicant performed a literature search in PubMed and the Cochrane Library using the search terms “lipid peroxidation”, “oxidized low density lipoprotein”, “oxidized lipids”, “cardiovascular disease”, “lipid oxidative damage” and “oxidative stress” cross-referenced with “vegetables”, “green vegetables”, “green leafy vegetables”, “spinach”, “chard”, “chicory” and “barley” for reports published from 1966 to February 2013. Bibliographies and studies suggested by search engines were also used to further increase the range of data collected. Human studies were included if they had adequate control groups and if they reported on markers of lipid peroxidation, which had to be measured before and after the study intervals. Animal and *in vitro* studies were included if they provided evidence on the mechanisms by which the food could exert the claimed effect, and on the biological plausibility of the specific claim.

The applicant identified one unpublished human study, 13 published human studies, nine animal studies, eight *in vitro* studies, eight guidelines/consensus opinions and 21 supportive studies (human mechanistic studies, meta-analyses and studies on bioavailability) as being pertinent to the health claim.

None of the published human, animal, *in vitro* or supportive studies were carried out with, or referred to, a food complying with the characterisation of the food which is the subject of the claim. The guidelines/consensus opinions did not contain data on a food complying with the characterisation of the food which is the subject of the claim. The Panel notes that none of these references can be used for the scientific substantiation of the claim.

Only one study (Bacchetti and Ferretti, unpublished, claimed as proprietary by the applicant) was provided which was carried out with the food (i.e. barley soup “Orzotto”) which is the subject of the health claim. This study was an open label single-arm (no control group) intervention in which 38 healthy men and women consumed daily for two weeks a portion (i.e. 250 g) of barley soup “Orzotto”. Among the outcome measures provided, blood concentrations of oxidized LDL were an appropriate outcome measure to assess blood lipid oxidation (EFSA NDA Panel, 2011). However, the Panel considers that no conclusions can be drawn from this uncontrolled (single-arm) study for the scientific substantiation of the claim.



The Panel concludes that a cause and effect relationship has not been established between the consumption of barley soup “Orzotto” and protection of blood lipids from oxidative damage.

## CONCLUSIONS

On the basis of the data presented, the Panel concludes that:

- The food, barley soup “Orzotto”, which is the subject of the health claim, is sufficiently characterised.
- The claimed effect proposed by the applicant refers to the protection of blood lipids from oxidative damage. The target population proposed by the applicant is the general population. Protection of blood lipids from oxidative damage may be a beneficial physiological effect.
- A cause and effect relationship has not been established between the consumption of barley soup “Orzotto” and protection of blood lipids from oxidative damage.

## DOCUMENTATION PROVIDED TO EFSA

Health claim application on barley soup “Orzotto” and protection of blood lipids from oxidative damage pursuant to Article 13(5) of Regulation (EC) No 1924/2006 (Claim serial No: 0387\_IT). May 2013. Submitted by Italsur srl.

## REFERENCES

- Bacchetti T and Ferretti G, unpublished (claimed as proprietary by the applicant). Effect of consumption of vegetable soup “Orzotto” on lipid profile and lipid peroxidation: a short term human intervention study. Protocol No 211525. Polytechnic University of Marche (UNIVPM), Italy.
- EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2011. Guidance on the scientific requirements for health claims related to antioxidants, oxidative damage and cardiovascular health. EFSA Journal 2011;9(12):2474, 13 pp. doi:10.2903/j.efsa.2011.2474